K071289 pg.10f2

### 510(k) Summary

#### 1.0 SUBMITTER INFORMATION

1.1 Submitter: SHIMADZU MEDICAL SYSTEMS

20101 South Vermont Ave. Torrance, CA 90502-1328

PH: 310-217-8855 FX: 310-217-8869

1.2 Contact: Don Karle

1.3 Date: April 25, 2007

#### 2.0 DEVICE NAME

2.1 Proprietary Name: SDU-1200Pro

2.2 Common Name: Ultrasound Imaging System

2.3 Classification: Ultrasonic Pulsed Doppler Imaging System

FR # 892.1550, Product Code 90-IYN Ultrasonic Pulsed Echo Imaging System FR # 892.1560, Product Code 90-IYO

Diagnostic Ultrasound Transducer

FR # 892.1570, Product Code 90-ITX

2.4 Predicate Device: Shimadzu SDU-1200Pro (K061643, Jul./27/06)

# 3.0 DEVICE DESCRIPTION

The SDU-1200Pro is a mobile diagnostic ultrasound system. This system has flat linear array, convex linear and sector probe with a frequency range of approximately 1.5 to 15 MHz. It has B mode, M mode, Pulsed Doppler mode, Continuous Doppler mode, Real time 3D mode, Color mode, or in a combination of modes.

#### 4.0 INTENDED USE

The SDU-1200Pro is intended for the following applications:

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Fetal, Abdominal, Pediatric, Small Organs (Specify), Neonatal Cephalic, Adult Cephalic, Cardiac, Transrectal, Transvaginal, Peripheral Vascular, Musculo-skeletal Superficial and Musculo-skeletal Conventional.

## 5.0 SAFETY CONSIDERATIONS

SDU-1200Pro has been designed to meet the following voluntary and measurement standards:

- IEC 60601-1 Safety of Medical Electric Equipment
- UL60601-1:2003 Medical Electrical Equipment Part I: General Requirements for Safety
- AIUM NEMA UD2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment Revision 1 (AIUM 1998)
- AIUM NEMA UD3 Standard for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

JAN - 9 2008

Mr. Don Karle Manager, Customer Service Shimadzu Medical Systems USA 20101 South Vermont Avenue TORRANCE CA 90502

Re: K071289

Trade/Device Name: Diagnostic Ultrasound System SDU-1200Pro, system

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: December 18, 2007 Received: December 19, 2007

#### Dear Mr. Karle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Diagnostic Ultrasound System SDU-1200Pro, system, as described in your premarket notification:

### Transducer Model Number

<u>L040-075U</u>	<u>VA13R-035U</u>	<u>VA40R-035VNU</u>	EC10R-065VPU
L040-120U	<u>VA13R-050U</u>	<u>VA57R-0375WU</u>	S011-050U
L040-120HU	VA20R-035U	<u>VA57R-0375HU</u>	<u>S017-035U</u>
L070-075U	<u>VA40R-035U</u>	<u>TV11R-055U</u>	<u>S020-025U</u>
L072-050U	<u>VA40R-035HU</u>	<u>UB10R-065U</u>	·
<u>VA11R-055U</u>	<u>VA40R-035VPU</u>	EC11R-055U	•

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <a href="http://www.fda.gov/cdrh/industry/support/index.html">http://www.fda.gov/cdrh/industry/support/index.html</a>

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

Sincerely yours,

(n Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

Prescription Use (	Per 21	CFR	801.	.109)
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Ultrasound Device Indications Statement

Page 1 of 23.

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

						of Operat	10n				<b>,</b>
Clinical Application	Ā	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic		<u> </u>					<u>.</u>				
Fetal		P	P	P		P	P	P	Р.	P	N
Abdominal		P	P	P	,	P	P	P	P	P	N
Intra-operative (Specify)										: 	
Intra-operative Neurological											
Pediatric					·				·	1 F	
Small Organ (Specify) *		P	Р	P		Р	P	P	P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P		P	P	P	P	P	
Transesophageal											
Transrectal		P	P	P		P	P	P	P	P	N
Transvaginal		P	P	P		P	P	P	P	P	N
Transurethral											
Intravascular										1000	
Peripheral Vascular		P	P	P		P	P	P	P	P	
Laparoscopic											
Musculo-skeletal Conventional		P	P	P		P	P	P	P	P	
Musculo-skeletal Superficial		P	P	P		P	P	P	P	Р	
Other (Specify)	1	1	1					i .			

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:	
* Thyroid, Testicles, Breast	
** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)	
*** Real time 3D	
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Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number \_\_\_\_

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement

Page <u>2</u> of <u>23</u>.

510(k) Number (if known):

K071289

Device Name: <u>Diagnostic Ultrasound System SDU-1200Pro, L040-075U</u>

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

					Mode	e of Operat	ion				
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmoni c Imaging	Other (Specify) ***
Ophthalmic											
Fetal											
Abdominal					<u> </u>						
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
Small Organ (Specify) *		P	P	P		P	P	Р	P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiaç											·
Transesophageal			l								
Transrectal											
Transvaginal			<u></u>				-				
Transurethral			<u> </u>								
Intravascular		Ī -									
Peripheral Vascular		P	P	P		P	P	P	P	P	
Laparoscopic											
Musculo-skeletal Conventional		P	P	P		P	P	P	P	P	
Musculo-skeletal Superficial		P	P	P		P	P	P	Р	P	
Other (Specify)											

N= new indication; P= previously cleared by FDA; E	= added under Appendix E
Other Indications or Modes:	
* Thyroid, Testicles, Breast	
** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)	
*** Real time 3D	
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Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number <u>K071289</u>

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 3 of 23.

510(k) Number (if known):

Device Name: Diagnostic Ultrasound System SDU-1200Pro, L040-120U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic							· · · · · · · · · · · · · · · · · · ·				1
Fetal											
Abdominal											<u> </u>
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric										4.	
Small Organ (Specify) *		Р	P	P		P	P	P	P	P	
Neonatal Cephalic											
Adult Cephalic								* .			
Cardiac										··· -	
Transesophageal											
Transrectal										<del></del>	
Transvaginal								:		· · · · · · · · · · · · · · · · · · ·	
Transurethral				•				-		·	
Intravascular											
Peripheral Vascular		P	P	P		P	P	P	P	P	
Laparoscopic											1
Musculo-skeletal Conventional		P	P	P		P	P	P	P	P	
Musculo-skeletal Superficial		P	P	P		P	P	P	P	P	
Others (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:	
* Thyroid, Testicles, Breast	
** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)	
***Real time 3D	
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Radiological Devices

510(k) Number ...

Ultrasound Device Indications Statement Page 4 of 23.

510(k) Number (if known):

Device Name: Diagnostic Ultrasound System SDU-1200Pro, L040-120HU

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Clinical Application	À	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) +++
Ophthalmic											
Fetal			<u> </u>								
Abdominal									· .	18.4 1	<u> </u>
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric						,					
Small Organ (Specify) *		P	P	P		Р	P	P	P	P	
Neonatal						<del> </del>					
Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal									10.00		<u> </u>
Transrectal									-		
Transvaginal											
Transurethral			Ī .		-				-	· · · ·	
Intravascular											
Peripheral Vascular		P	Ρ	P		P	P	P	P	Р	
Laparoscopic										V	
Musculo-skeletal Conventional		P	P	P		P	P	P	P	P	
Musculo-skeletal Superficial		P	P	P		P	P	P	P	P	
Others (Specify)											-

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:		
* Thyroid, Testicles, Breast		
** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)		<del></del>
*** Real time 3D		
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510(k) Number

Prescription	Use	(Per	21	<b>CFR</b>	801.	.109)

Ultrasound Device Indications Statement Page <u>5</u> of <u>23</u>.

K071289

510(k) Number (if known): KUTLST

Device Name: Diagnostic Ultrasound System SDU-1200Pro, L070-075U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

					Mod	de of Opera	ation				<del> </del>
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic							<u> </u>				
Fetal					İ						
Abdominal							·				
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
Small Organ (Specify) *		P	Р	P		P	- P	P	P	P	
Neonatal						-					
Cephalic											
Adult Cephalic											
Cardiac			2		:			:			
Transesophageal				V							
Transrectal											
Transvaginal											
Transurethral											
Intravascular											<u> </u>
Peripheral Vascular		P	P	P		P	P	P	P	P	
Laparoscopic											
Musculo-skeletal Conventional		P	P	P		P	P	P	P	P	
Musculo-skeletal Superficial		P	P	P		P	P	P	P	P	
Others (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:		<u> </u>
* Thyroid, Testicles, Breast		
** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)		
*** Real time 3D		
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Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number .\_\_\_\_

Prescription Use (Per 21 CFR 801.109)	
Ultrasound Device Indications Statement	

Page <u>6</u> of <u>23</u>.

510(k) Number (if known):

K071289

Device Name: Diagnostic Ultrasound System SDU-1200Pro, L072-050U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color	Power	Color	Combined	Tissue	Other
						Doppler	(Amplitude) Doppler	Velocity Imaging	(Specify)**	Harmonic Imaging	(Specify)
Ophthalmic											Ì
Fetal											
Abdominal										- 1 - W	
Intra-operative (Specify)									,		,
Intra-operative	<del> </del>										
Neurological		<u> </u>	ŀ							1.5%	
Pediatric											
Small Organ (Specify) *		P	P	P		P	P	Р	P	P	
Neonatal							1				<u>"</u>
Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal						,			٠.		
Transrectal	<u> </u>	<u> </u>									
Transvaginal											
Transurethral											
Intravascular										-	
Peripheral Vascular		P	P	P		Ţ.	P	P	P	P	
Laparoscopic											
Musculo-skeletal		P	P	P		P	P	P	P	P	
Conventional											
Musculo-skeletal											
Superficial											
Others (Specify)	<u>L</u> .										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:	
* Thyroid, Testicles, Breast	
** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)	
*** Real time 3D	
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Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number \_\_\_\_

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Prescription	Use	(Per 21	<b>CFR</b>	801	.109)
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Ultrasound Device Indications Statement Page  $\underline{7}$  of  $\underline{23}$ .

510(k) Number (if known): \_\_\_\_\_\_\_ K 511289

Device Name: Diagnostic Ultrasound System SDU-1200Pro, VA11R-055U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

					Mod	ie of Opera	non				
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic									<u> </u>		
Fetal		P	P	P		P	P	P	P	P	
Abdominal		P	P	P		P	P	P	P	P	
Intra-operative (Specify)											
Intra-operative Neurological											·
Pediatric:	ļ	P	P	P		P	P	P	P	P	
Small Organ (Specify) *											
Neonatal Cephalic		P	P	P		P	P	P	P	P	
Adult Cephalic		P	P	P		P	P	P	P	P	
Cardiac		P	P	P		P	P	P	P	P	
Transesophageal											
Transrectal											
Transvaginal	Ī										
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic					-						
Musculo-skeletal Conventional											
Musculo-skeletal Superficial				<del></del> .							
Others (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:		
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)		
*** Real time 3D		
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Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number K011289

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Ultrasound Device Indications Statement

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510(k) Number (if known):

K671289

Device Name : <u>Diagnostic Ultrasound System SDU-1200Pro, VA13R-035U</u>

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

			<u></u>		IVIO	te of Opera	nion				
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic											
Fetal		P	P	P		P	P	P	P	P	
Abdominal	1	P	P	P	]	P	P	P	P	P	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric	I		[								
Small Organ (Specify) *											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P		P	P	P	P	P	
Transesophageal											
Transrectal											
Transvaginal				,							
Transurethral											
Intravascular										and the	
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional										·	i
Musculo-skeletal Superficial							· · · · · · · · · · · · · · · · · · ·				
Others (Specify)		:									

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:	
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)	
*** Real time 3D	
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Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number \_

Ultrasound Device Indications Statement Page 9 of 23.

510(k) Number (if known):

Device Name: Diagnostic Ultrasound System SDU-1200Pro, VA13R-050U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic	_		-								
Fetal		P	P	P	<del></del> -	.P	P	P	P	P	
Abdominal		P	P	P		P	Р.	P	P	P	
Intra-operative (Specify)											
Intra-operative Neurological							<u> </u>	,			
Pediatric							· ·				
Small Organ (Specify) *											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P		P	P	P	P	P	
Transesophageal		l									
Transrectal									· ·		
Transvaginal					<u> </u>						
Transurethral									ļ		
Intravascular						<u> </u>					
Peripheral Vascular											
Laparoscopic											ļ
Musculo-skeletal Conventional									,	•	
Musculo-skeletal Superficial											
Others (Specify)							1				

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:					
** B/M, B/PWD, CFM(B)/PWD,CFM(	(B)/CFM(M)				
*** Real time 3D					
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Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number \_\_\_\_

Ultrasound Device Indications Statement Page 10 of 23.

510(k) Number (if known): \( \text{NU II \( \text{LSY} \)} \)

Device Name: \( \text{Diagnostic Ultrasound System SDU-1200Pro, VA20R-035U} \)

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

					IVIO	te of Opera	tion				
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic					<u>L</u>						
Fetal		P	P	P		P	P	P	P	P	
Abdominal	<u> </u>	P	P	P		P	P	P	P	P	,
Intra-operative (Specify)		:								- <i>C</i>	
Intra-operative Neurological											
Pediatric											
Small Organ (Specify) *											
Neonatal Cephalic											·
Adult Cephalic	-			<del></del>				·			
Cardiac	<del> </del>	P	P	P		P				<u> </u>	
Transesophageal	<del>                                     </del>	r	F	_ <u>r</u>		<u> </u>	P	P	P	P	
Transesophageat	-										
Transvaginal	-					· · · · · · · · · · · · · · · · · · ·					
Transurethral	-							· ·			<del></del>
Intravascular	<del> </del>										
Peripheral Vascular						·					
Laparoscopic								<u> </u>			
Musculo-skeletal							<u></u>				
Conventional				İ			:				
Musculo-skeletal Superficial								·			
Others (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:	
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)	
*** Real time 3D	
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Concurrence of CDRH, Office of Device Evaluation (O	

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number \_

Prescription	Use (	Per 21	<b>CFR</b>	801	.109)
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Ultrasound Device Indications Statement

Page 11 of 23.

510(k) Number (if known):

K011289

Device Name: Diagnostic Ultrasound System SDU-1200Pro, VA40R-035U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

					Mod	le of Opera	tion				
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic											
Fetal		P	P	P		P	P	P	P	P	
Abdominal		P	P	Ρ.		P	P	P	P	P	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
Small Organ (Specify) *						,	:				
Neonatal Cephalic											
Adult Cephalic	1		i								
Cardiac											
Transesophageal											
Transrectal											
Transvaginal							-				
Transurethral											
Intravascular											
Peripheral Vascular			]								
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:	
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)	
*** Real time 3D	
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	
Concurrence of CDRH, Office of Device Evaluation (ODE)	

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Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number \_\_\_\_

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Prescription Use (P											
Ultrasound Device Indications Statement Page 12 of 23.											
V M10 00											
510(k) Number (if known):											
Device Name: Dia	ignos	tic L	Jltras	ound S	ystem S	DU-1200P	ro, VA40R-0	35HU			
					_			<del></del>			
Fill out on	e for	m fo	r eac	h ultras	ound sy	stem or tra	nsducer.				
Indications for use:	Dia	gno	stic u	ltrasoui	nd imag	ing or Dop	pler analysis	of the hum	an body as fo	llows:	
					Мос	de of Opera	tion				
Clinical	A	В	М	PWD	CWD	Color	Power	Color	Combined	Tissue	Other
Application				l E		Doppler	(Amplitude)	Velocity	(Specify)**	Harmonic	(Specify)
Ophthalmic							Doppler	Imaging		Imaging	***
Fetal		P	P	P		P	P	P	P	P	
Abdominal		P	P	P		P	P	P	P	P	
Intra-operative	-								1	-	
(Specify)				i							
Intra-operative									<del> </del>	<del></del>	
Neurological								*			
Pediatric									<u> </u>		
Small Organ									1		
(Specify) *											
Neonatal							_				_
Cephalic											,
Adult Cephalic											
Cardiac	,										
Transesophageal											
Transrectal								· <del>- · · · · · · · · · · · · · · · · · · </del>			
Transvaginal											
Transurethral									<u> </u>		
Intravascular											
Peripheral Vascular									<del> </del>		
Laparoscopic											
Musculo-skeletal										·	-
Conventional											
Musculo-skeletal											
Superficial		_	_								
Others (Specify)											
N= new indication: I	D= n	evic	neliv	cleared	h. DD	A. De adda	d wardon Amm				

Others (Specify)								
N= new indication; l	P= prev	iously cle	ared by FD	A; E= adde	d under App	endix E	<u> </u>	<del></del>
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Other Indications or								
** B/M, B/PWD, CI	M(B)/I	PWD,CF	M(B)/CFM	(M)				
*** Real time 3D								
						·· - ···	<del> </del>	
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Prescription Use (Per 21 CFR 801.109)
Ultrasound Device Indications Statement Page 13 of 23
510(k) Number (if known): V11289 Device Name: Diagnostic Ultrasound System SDU-1200Pro, VA40R-035VPU
Fill out one form for each ultrasound system or transducer.
Tuding C D to the state of the

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation PWD CWD Clinical В М Color Color Combined Tissue Other Doppler (Amplitude) Velocity (Specify)\*\* Application (Specify) \*\*\* Harmonic Doppler Imaging Imaging Ophthalmic Fetal N. N N N Ν N N N N Abdominal N N N N N N N N Intra-operative (Specify) Intra-operative Neurological Pediatric<sup>\*</sup> Small Organ (Specify) \* Neonatal Cephalic Adult Cephalic Cardiac Transesophageal Transrectal Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial Others (Specify)

N= new indication; P= previously cleared by FDA; E= added under Appendix E
Other Indications or Modes:
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)
*** Real time 3D
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Concurrence of CDRH, Office of Device Evaluation (ODE)
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Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number \_\_\_\_\_ K 071289

Prescription Use (Per 21 CFR 801.109)	
Ultrasound Device Indications Statement	Page <u>14</u> of <u>23</u> .
510(k) Number (if known): K011289	
Device Name: Diagnostic Ultrasound System SDU-1200Pro, VA4	<u>0R-035VNU</u>
Eill	

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

					IVIO	ie of Opera	uon				
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic				<u> </u>							
Fetal		N	N	N		N	N	N	N	N	N
Abdominal		N	N	N		N	N	N	N	N	N
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
Small Organ (Specify) *											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal	1										
Transrectal					-						
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional										•	<u> </u>
Musculo-skeletal Superficial											
Others (Specify)											<u> </u>

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:		
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)	 	
*** Real time 3D		
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Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number \_\_\_

Prescription Use (Per 21 CFR 801.109)
Ultrasound Device Indications Statement Page 15 of 23
510(k) Number (if known): K011289  Device Name: Diagnostic Ultrasound System SDU-1200Pro, VA57R-0375WU
Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude)	Color Velocity	Combined (Specify)**	Tisșue Harmonic	Other (Specify)
	<u> </u>				<u> </u>		Doppler	Imaging		Imaging	***
Ophthalmic									<u> </u>		
Fetal		P	P	P		Р	P	P	P	P	
Abdominal		P	P	P		P	P	P	P	P	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric									<del> </del>		
Small Organ (Specify) *											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal						-					
Transvaginal											i
Transurethral											
Intravascular										-	
Peripheral Vascular							·				
Laparoscopic					, ,						
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

	Muscuto-sketetat
	Superficial
	Others (Specify)
,	N= new indication; P= previously cleared by FDA; E= added under Appendix E
	Other Indications or Modes:
	** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)
	*** Real time 3D
	(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
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Ultrasound Device Indications Statement Page 16 of 23.

510(k) Number (if known): 10 11 40

Device Name: Diagnostic Ultrasound System SDU-1200Pro, VA57R-0375HU

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

F					10100	ie of Opera	шоп				
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic			j		<u> </u>	<u>.</u>					
Fetal		P	P	P		P	P	P	P	P	
Abdominal		P	P	P		·P	P	P	P	P	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric						-				1.	
Small Organ (Specify) *											
Neonatal Cephalic											
Adult Cephalic	l								· ·		
Cardiac											<u> </u>
Transesophageal											
Transrectal			l								
Transvaginal								· · · · · · · · · · · · · · · · · · ·			
Transurethral											
Intravascular										7	
Peripheral Vascular									<del></del>		
Laparoscopic									-	· · · · · ·	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

N= new indication; P= prev	riously cleared by FDA; E= added under App	endix E
Other Indications or Modes	n.	
** B/M, B/PWD, CFM(B)/	PWD,CFM(B)/CFM(M)	
*** Real time 3D		
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	Concurrence of CDRH, Office of Device Evaluation (OD	)E)
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	Division of Reproductive, Abdomin	ial and
	Radiological Devices 510(k) Number	2.89

Prescription Use	(Per 21	<b>CFR</b>	801.	109)	į
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Ultrasound Device Indications Statement

Page 17 of 23.

510(k) Number (if known):\_

Device Name : Diagnostic Ultrasound System SDU-1200Pro, TV11R-055U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

	<del></del>				Mod	de of Opera	ition	_			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic	<u> </u>	<u> </u>	'								
Fetal		P	P	P		.P	P	P	P	P	
Abdominal	$\prod$										<del> </del>
Intra-operative (Specify)						-			:		
Intra-operative Neurological											
Pediatric										<del></del>	<del>                                     </del>
Small Organ (Specify) *											
Neonatal Cephalic											
Adult Cephalic	$\vdash$				<u> </u>		<del>                                     </del>	<u></u>		<u> </u>	<del> </del>
Cardiac											<del> </del>
Transesophageal		· · ·		<del></del>			-				<del> </del>
Transrectal		P	P	P	*	P	P	<b>P</b> ·	P	P	<del> </del>
Transvaginal		P	P	P	Ţ	P	P	P	P	P	<del> </del>
Transurethral						· · · · · · · · ·					<del> </del>
Intravascular										-	<del> </del>
Peripheral Vascular											
Laparoscopic											<del> </del>
Musculo-skeletal								· · · · · · · · · · · · · · · · · · ·			<del> </del>
Conventional				!							
Musculo-skeletal										<del></del>	
Superficial						ı					
Others (Specify)								<del></del>			

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:  ** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)				<u> </u>
*** Real time 3D		· . ··		
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Division of Reproductive, Abdominal and

**Radiological Devices** 

510(k) Number

Prescription Use (Po Ultras 510(k) Number (if k Device Name : <u>Dia</u> Fill out one	sour mow gnos	nd D	evio	ce Indi	112{ ystem S	<u>DU-1200</u> Pi			23		
Indications for use:	Dia	ignos	stic u	ltrasoui	nd imag	ing or Dop	pler analysis	of the huma	n bódy as fol	lows:	
					Mod	ie of Opera	ition			·	
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic				<u> </u>							
Fetal										1 .	
Abdominal											
Intra-operative											
(Specify)											
Intra-operative										. *	
Neurological				ž.,							
Pediatric											<u> </u>
Small Organ					1						
(Specify) *		<u> </u>		,	<u> </u>						<u> </u>
Neonatal											
Cephalic	ļ	ļ	<u> </u>						ļ <u></u>	· · · · · · · · · · · · · · · · · · ·	
Adult Cephalic	ļ	<u> </u>	ļ	<u> </u>					· .		
Cardiac	<u> </u>		<u> </u>			<u> </u>	<u> </u>		ļ		
Transesophageal		<u> </u>	<u> </u>								
Transrectal		P	P	P		P	P	P	P	P	
Transvaginal	<u> </u>			<u> </u>	ļ						
Transurethral		<u> </u>									
Intravascular											
Peripheral Vascular			<u> </u>	<u> </u>		<u> </u>					
Laparoscopic	L	<u> </u>		<u> </u>							<u> </u>
Musculo-skeletal		1								·	
Conventional			<u> </u>	<u> </u>					<u> </u>		
Musculo-skeletal									1		
Superficial	<u> </u>		<u> </u>		<u> </u>					ļ	
Others (Specify)		<u> </u>			<u> </u>	<u>                                     </u>					

Superficial									
Others (Specify)									
N= new indication;	P= pr	eviously o	cleared by I	DA; E= ac	dded under	Appendix E		•	
Other Indications	r Mod	es:							
** B/M, B/PWD, 0	CFM(E	3)/PWD,C	FM(B)/CF	M(M)					_
*** Real time 3D									
							<u> </u>		
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Prescription Use (Per 21 CFR 801.109)			
	e 19	of 2	3
510(k) Number (if known): 2511289 Device Name: Diagnostic Ultrasound System SDU-1200Pro, EC11R-0	)55 <u>U</u>		

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic			ļ								
Fetal		P	P	Р		P	P	P	P	P	
Abdominal											T
Intra-operative (Specify)									-		
Intra-operative Neurological											
Pediatric											
Small Organ (Specify) *							· ·				
Neonatal Cephalic					-						
Adult Cephalic											1
Cardiac				·					<del></del>		1
Transesophageal											<del>                                     </del>
Transrectal		P	P	P		P	P	P	P	P	1
Transvaginal		P	P	P		P	P	P	P	P	1
Transurethral										<u></u>	1
Intravascular											1
Peripheral Vascular									1		
Laparoscopic											1
Musculo-skeletal Conventional										;	
Musculo-skeletal Superficial								;			
Others (Specify)		1	1			<del> </del>				<b>†</b>	1

Conventional											Ì	
Musculo-skeletal								:				1
Superficial					1							
Others (Specify)												
N= new indication;	P= p	revi	ously	cleare	d by FI	A; E≔ ad	ded under	Appendix E				
Other Indications o	r Mo	des:										
** B/M, B/PWD, C	FM(	B)/P	WD,	CFM(I	3)/CFM	(M)					•	
*** Real time 3D												
					·							_
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510(k) Number \_

Prescription Use (Per 21 CFR 801.109)	
Ultrasound Device Indications Statement	Page <u>20</u> of <u>23</u>
510(k) Number (if known): K071289.	
Device Name · Diagnostic Illtrasound System SDII-1200Pro EC	10R-065VPU

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic				_			1. 1/				<del> </del>
Fetal		N	N	N		N	N	N	N	N	N
Abdominal				,					1.		
Intra-operative (Specify)											1:
Intra-operative Neurological											
Pediatric											
Small Organ (Specify) *					-						
Neonatal Cephalic											
Adult Cephalic									·	11	
Cardiac								:		· · · · ·	<del> </del>
Transesophageal											
Transrectal	L	N	N	N		N	N	N	N	N	N
Transvaginal		N	N	N		N	N	N	N	N	N
Transurethral							T				
Intravascular										T.	
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional								-			
Musculo-skeletal Superficial											
Others (Specify)			<u> </u>	· -							<del> </del>

Conventional	1 1 1		]			-		
Musculo-skeletal							<del>-  </del> -	$\neg$
Superficial								•
Others (Specify)								
N= new indication; P=	previously cleare	d by FDA;	E= added un	der App	endix E	· · · · · · · · · · · · · · · · · · ·		
Other Indications or M	odes:	=		_				
** B/M, B/PWD, CFM	(B)/PWD,CFM(I	B)/CFM(M	)					
*** Real time 3D						· · · · · · · · · · · · · · · · · · ·		
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	Concurren	nce of CDRH, O	ffice of Device Ev	aluation (OI	DE)			
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Ultrasound Device Indications Statement

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510(k) Number (if known):

Device Name: Diagnostic Ultrasound System SDU-1200Pro, S011-050U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

					Mod	ie of Opera	tion	*************	<u> </u>		
Clinical Application	A	В	M	PWD	CWD	Còlar Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic											
Fetal				<u> </u>							
Abdominal				P		P	P			P	
Intra-operative (Specify)											
Intra-operative Neurological										,	
Pediatric		P	P	P	P	P	P	P	P	P	
Small Organ (Specify) *											
Neonatal Cephalic						,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,					
Adult Cephalic			1								-
Cardiac		P	P	P	P	P	P	P	P	P	<u> </u>
Transesophageal	1				7						ļ
Transrectal										,	
Transvaginal											
Transurethral										· · · · · ·	
Intravascular											1
Peripheral Vascular							-				
Laparoscopic											1
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)							<b></b>	-			

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/PWD,CFM(M),B/CWD,CFM(B)/CWD
Harmonic Imaging
*** Real time 3D
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510(k) Number \_

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page

Page <u>22</u> of <u>23</u>.

510(k) Number (if known):

K071289

Device Name: Diagnostic Ultrasound System SDU-1200Pro, S017-035U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

	<del></del>	<del></del>		<del></del>		de of Opera	ition	<del></del>			
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic	<u> </u>			<u></u> '		<u></u>	<u></u>		T		
Fetal		$\perp$					T				
Abdominal		<u> </u>		P		P	P			P	
Intra-operative (Specify)										-	
Intra-operative Neurological											
Pediatric				<u> </u>							
Small Organ (Specify) *											
Neonatal Cephalic								·			
Adult Cephalic	<u> </u>			· '							<del> </del>
Cardiac		Р	P	P	P	P	P	P	P	P	<b></b>
Transesophageal										<del>-</del>	<del></del>
Transrectal											<u> </u>
Transvaginal					<u> </u>						<u> </u>
Transurethral									-		<u>                                     </u>
Intravascular											
Peripheral Vascular											<u> </u>
Laparoscopic											<u> </u>
Musculo-skeletal											
Conventional	<u> </u>	<u> </u>		<u>                                     </u>	<u> </u>		<u> </u>				1
Musculo-skeletal				1							
Superficial	<b>└</b>	<b></b> '	<u> </u>	!		L		l	<u>.</u>	<b>i</b>	1
Others (Specify)	1 '	$1 \cdot 1$	'	$\bar{l}$	[ /						

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:	
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/PWD,CFM(B)/CFM(M),B/CWD,CFM(B)/CWD	-
Harmonic Imaging	_
*** Real time 3D	_
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	_
Concurrence of CDRH, Office of Device Evaluation (ODF)	-

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

071289

Prescription Use (Per 21 CFR 801.109)					
Ultrasound Device Indications Statement	Page_	23	of_	23	_
510(k) Number (if known):   < 071289					
Davice Name: Diagnostic Hitrogrand System CDH 1200Dre C	ימים מסבדד				

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Obj. 14 to the	<del>i .</del>		T	DIVE		te of Opera		1	T	T	
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify) ***
Ophthalmic											
Fetal											
Abdominal				P		P	P			Р	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
Small Organ (Specify) *											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P	P	P	P	
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular		İ									
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal											
Conventional	<del> </del>	<del> </del>	<b>_</b>	<u></u>	ļ		<u> </u>	<u> </u>	<u> </u>		ļ
Musculo-skeletal Superficial											
Others (Specify)											1

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/PWD,CFM(B)/CFM(M),B/CWD,CFM(B)/CWD
Harmonic Imaging
*** Real time 3D
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

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Radiological Devices 510(k) Number \_\_\_\_\_ K 511 289